CURRICULUM VITAE

Name: Boris Freidlin

Office Address:

Biostatistics Branch
Biometric Research Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute
9609 Medical Center Drive, Room 5W102 MSC9735
Bethesda, MD 20892-9735
(240) 276 - 6024 (office)
(240) 276 - 7888 (fax)
freidlinb@ctep.nci.nih.gov

Education:

1998	Ph.D., Statistics George Washington University, Washington, DC
1992	M.S., Applied Statistics George Washington University, Washington, DC
1988	B.S., Mathematics University of Maryland, College Park, MD

Professional Experience:

2019-present	Branch Chief, Biostatistics Branch, Biometric Research Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, Bethesda, MD
1998-2019	Mathematical Statistician, Biometric Research Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, Bethesda, MD
1993-1998	Statistician, The EMMES Corporation, Potomac, MD
1992-1993 1989-1992	Statistician, Synectics, Arlington, VA Research Assistant, GWU Biostatistics Center, Rockville, MD

Selected Professional Activities:

Associate editor: Clinical Trials

Referee for American Journal of Epidemiology, Annals of Oncology, Biometrical Journal, Biometrics, Biometrika, Clinical Cancer Research, Clinical Trials, Journal of Clinical Oncology, Journal of the National Cancer Institute, Nature Reviews Clinical Oncology, Pharmaceutical Statistics and Statistics in Medicine.

Awards:

American Statistical Association Outstanding Statistical Application Award (2002).

Professional Societies:

American Statistical Association

Publications:

- 1. Trimble E, Carter C, Cain D, **Freidlin B**, Ungerleider R, Friedman M. Representation of older patients in cancer treatment trials. *Cancer Supplement* 74:2208-2214, 1994
- 2. Pompetti F, Rizzo P, Simon R, **Freidlin B**, Mew D, Pass H, Picci P, Levine A, Carbone M. Oncogene alterations in primary, recurrent and metastatic human bone tumors. *Journal of Cellular Biochemistry* 63:37-50, 1996
- 3. Simon R, **Freidlin B**, Rubinstein L, Arbuck S, Collins J, Christian M. Accelerated titration designs for phase I clinical trials in oncology. *Journal of the National Cancer Institute* 89:1138-1147, 1997
- 4. Becker KG, Simon RM, Bailey-Wilson J, **Freidlin B**, Biddison W, McFarland H, Trent J. Clustering of non-MHC susceptibility candidate loci in human autoimmune diseases. *Proceedings of National Academy of Science* 17:9979-9984, 1998
- 5. Smith M, **Freidlin B**, Gloeckler Reis LA, Simon R. Trends in the reported incidence of primary malignant brain tumors in children in the United States. *Journal of the National Cancer Institute* 90:1269-1277, 1998
- 6. **Freidlin B**, Gastwirth JL. Unconditional versions of several tests commonly used in the analysis of contingency tables. *Biometrics* 55:84-89, 1999

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- 8. **Freidlin B**, Podgor MJ, and Gastwirth, JL. Efficiency robust tests for survival and ordered categorical data. *Biometrics* 55:883-886, 1999
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- 10. Cheson BD, Vena DA, Barrett J, **Freidlin B**. Second malignancies as a consequence of nucleoside analog therapy for chronic lymphoid leukemias. *Journal of Clinical Oncology* 17:2454-2460, 1999
- 11. Bubley GJ, Carducci M, Dahut W, Dawson N, Daliani D, Eisenberger M, Figg WD, **Freidlin B**, et al. Eligibility and response guidelines for phase II clinical trials in androgen-independent prostate cancer: recommendations from the Prostate-Specific Antigen Working Group. *Journal of Clinical Oncology* 17: 3461-3467, 1999
- 12. **Freidlin B**, Gastwirth JL. Should the median test be retired from the general use? *American Statistician* 54:161-164, 2000
- 13. Gastwirth, JL, **Freidlin B**. On power and efficiency robust linkage tests for affected sibs. *Annals of Human Genetics*, 64:443-453, 2000
- 14. **Freidlin B,** Gastwirth JL Changepoint tests designed for the analysis of hiring data arising in employment discrimination cases. *Journal of Business and Economic Statistics* 18:315-322, 2000
- 15. Breathnach OS, **Freidlin B**, Conley B, Green MR, Johnson DH, Gandara DR, O'Connell M, Shepherd FA, Johnson BE. Twenty-two years of phase III trials for patients with advanced non-small-cell lung cancer: sobering results. *Journal of Clinical Oncology* 19(6):1734-1742, 2001
- 16. **Freidlin B**, Korn EL A testing procedure for survival data with few responders. *Statistics in Medicine* 21:65-78, 2002
- 17. **Freidlin B**, Dancey J, Korn EL, Zee B, and Eisenhauer E. Multinomial phase II trial designs (letter). *Journal of Clinical Oncology* 20:599, 2002
- 18. Zheng G, **Freidlin B**, Gastwirth JL. Robust TDT-type candidate gene association tests. *Annals of Human Genetics* 66:145-155, 2002
- 19. **Freidlin B** and Korn EL. A comment on futility monitoring. *Controlled Clinical Trials* 23:355-356, 2002

- 20. **Freidlin B**, Zheng G, Li Z, Gastwirth JL. Trend tests for case-control studies of genetic markers: power, sample size and robustness. *Human Heredity*, 53:146-152, 2002
- 21. Jane PA, **Freidlin B**, Saxman S, et al. Twenty-five years of clinical research for patients with limited-stage small cell lung carcinoma in North America Meaningful improvements in survival. *Cancer* 95, 1528-1538, 2002
- 22. McShane LM, Radmacher MD, **Freidlin B**, et al. Methods for assessing reproducibility of clustering patterns observed in analyses of microarray data. *Bioinformatics* 18:1462-1469, 2002
- 23. **Freidlin B**, Breathnach OS, Johnson BE. A model to select regimens for phase III trials for patients with advanced-stage non-small cell lung cancer. *Clinical Cancer Research* 9:917-922, 2003
- 24. Zheng G, **Freidlin B**, Li ZH, Gastwirth JL. Choice of scores in trend tests for case-control studies of candidate-gene associations. *Biometrical Journal* 45:335-348, 2003
- 25. Dancey JE, **Freidlin B**. Targeting epidermal growth factor receptor are we missing the mark? *Lancet* 362:62-64, 2003
- 26. **Freidlin B**, Zheng G, Li ZH, Gastwirth JL. Efficiency robust tests for mapping quantitative trait loci using extremely discordant sib pairs. *Human Heredity* 55:117-124, 2003
- 27. **Freidlin B**, Miao W, Gastwirth JL. On the use of the Shapiro-Wilk test in two-stage adaptive inference for paired data from moderate to very heavy tailed distributions. *Biometrical Journal* 45:887-900, 2003
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- 29. Korn EL, **Freidlin B**, Gorge SL. Data monitoring and large apparent treatment effects (letter). *Controlled Clinical Trials* 25:67-69, 2004
- 30. **Freidlin B**, Korn EL. A testing procedure for survival data with few responders (letter) *Statistics in Medicine* 23:1818-1823, 2004
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- 33. Gastwirth JL, **Freidlin B**. A note on appropriate use of statistical tests of mutation rates from ordered groups. *Genetic Testing* 8:437-440, 2004
- 34. Zheng G, **Freidlin B**, Li ZH, Gastwirth JL. Genomic control for association studies under various genetic models. *Biometrics* 61:187-193, 2005
- 35. **Freidlin B**, Korn EL. Testing treatment effects in the presence of competing risks. *Statistics in Medicine* 24:1703-1712, 2005
- 36. **Freidlin B**, Simon R. An evaluation of randomized discontinuation design. *Journal of Clinical Oncology* 23:5094-5098, 2005
- 37. Korn EL, Hunsberger S, **Freidlin B**, Smith MA, Abrams JS. Preliminary data release for randomized clinical trials of noninferiority: a new proposal. *Journal of Clinical Oncology* 23:5831-5836, 2005
- 38. Rubinstein LV, Korn EL, **Freidlin B**, Hunsberger S, Ivy SP, Smith MA. Design issues of randomized phase II trials and a proposal for phase II screening Trials. *Journal Of Clinical Oncology* 23:7199-7206, 2005
- 39. **Freidlin B**, Simon R. Adaptive signature design: An adaptive clinical trial design for generating and prospectively testing a gene expression signature for sensitive patients. *Clinical Cancer Research* 11:7872-7878, 2005
- 40. Zheng G, **Freidlin B**, Gastwirth JL. Robust genomic control for association studies. *The American Journal of Human Genetics* 78: 350-356, 2006
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- 42. Korn EL, **Freidlin B**. Conditional power calculations for clinical trials with historical controls. *Statistics in Medicine* 25:2922-2931, 2006
- 43. **Freidlin B**, Korn EL. Letter to the editor Testing treatment effects in the presence of competing risks. *Statistics in Medicine* 25:3761-3763, 2006
- 44. Korn EL, Freidlin B. A posterior tale. *Biometrical Journal* 49: 346-50, 2007
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- 54. Dodd LE, Korn EL, **Freidlin B**, Jaffe CC, Rubinstein LV, Dancey J, Mooney MM. Blinded independent central review of progression-free survival in phase III clinical trials: important design element or unnecessary expense? *Journal of Clinical Oncology* 26:3791-6, 2008
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- estimation. Clinical Trials 6:119-25, 2009
- 58. **Freidlin B**, Jiang W, Simon R. The cross-validated adaptive signature design. *Clinical Cancer Res*earch 16:691-8, 2010
- 59. **Freidlin B**, McShane LM, Korn EL. Randomized Clinical Trials With Biomarkers: Design Issues. *Journal of the National Cancer Institute* 102:152-160, 2010
- 60. Korn EL, **Freidlin B**, Mooney M. Bias in trials stopped early for benefit. (letter) *Journal of the American Medical* Association 304:157-158, 2010
- 61. **Freidlin B**, Korn EL, Gray R. A general inefficacy interim monitoring rule for randomized clinical trials. *Clinical Trials* 7:197-208, 2010
- 62. Korn EL, **Freidlin B**, Mooney M, Abrams JS. Accrual experience of National Cancer Institute Cooperative Group phase III trials activated from 2000 to 2007. *Journal of Clinical Oncology* 28:5197-201, 2010
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- 70. Korn EL, **Freidlin B**, Abrams JS. Overall survival as the outcome for randomized clinical trials with effective subsequent therapies. *Journal of Clinical Oncology* 29:2439-2442, 2011

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- 73. Korn EL, **Freidlin B**, Abrams JS and Halabi S. Design issues in randomized phase II/III trials. *Journal of Clinical Oncology* 30:667-671, 2012
- 74. Korn EL, **Freidlin B** and Abrams JS. Bevacizumab in ovarian cancer (letter). *New England Journal of Medicine* 366:1256, 2012
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- 78. Lawrence YR, Vikram B, Dignam JJ, Chakravarti A, Machtay M, **Freidlin B**, et al: NCI-RTOG Translational Program Strategic Guidelines for the Early-Stage Development of Radiosensitizers. *Journal of the National Cancer Institute* 105:11-24, 2013
- 79. **Freidlin B**, Korn EL. Borrowing Information Across Subgroups: Is It Useful? *Clinical Cancer Research* 19:1326-1334, 2013
- 80. **Freidlin B**, Korn EL. Adaptive randomization versus interim Monitoring. *Journal of Clinical Oncology* 31:969-970, 2013
- 81. Korn EL, McShane LM, **Freidlin B**. Statistical challenges in the evaluation of treatments for small patient populations *Science Translational Medicine*, 5 (178), art. no. 178sr3, 2013
- 82. **Freidlin B**, Sun Z, Gray R, Korn EL. Phase III clinical trials that integrate treatment and biomarker evaluation. *Journal of Clinical Oncology* 31: 3158-3161, 2013
- 83. **Freidlin B**, Abrams JS, Korn EL. New challenges for comparative effectiveness in oncology: Choice of primary end points for randomized clinical trials. *Journal of Comparative Effectiveness Research*, 2: 469-481, 2013

- 84. Dodd LE, Korn EL, **Freidlin B**, Gu W, Abrams JS, Bushnell WD, Canetta R, Doroshow JH, Gray RJ, Sridhara R. An audit strategy for time-to-event outcomes measured with error: Application to five randomized controlled trials in oncology. *Clinical Trials*, 10:754-760, 2013
- 85. Polley M-Y, **Freidlin B**, Korn EL, Conley BA, Abrams JS, McShane LM. Statistical and practical considerations for clinical evaluation of predictive biomarkers. *Journal of the National Cancer Institute*, 105:1677-1683, 2013
- 86. **Freidlin B**, Korn EL. Biomarker enrichment strategies: Matching trial design to biomarker credentials *Nature Reviews Clinical Oncology*, 11: 81-90, 2014
- 87. **Freidlin B**, Korn EL, Gray R. Marker Sequential Test (MaST) design *Clinical Trials*, 11: 19-27, 2014
- 88. **Freidlin B**, Korn EL. Transparency in interim monitoring *Journal of Clinical Oncology*, 32:2387-2388, 2014
- 89. **Freidlin B**, Sun Z, Gray R, Korn EL. Reply to Goteti et al. *Journal of Clinical Oncology* 32: 856, 2014
- 90. **Freidlin B**, Korn EL. A model too far. *Journal of the National Cancer Institute*, 106(2):djt638, 2014
- 91. **Freidlin B**, Korn EL. Response to Etzioni and Gulati. *Journal of the National Cancer Institute*, 106(4):dju059, 2014
- 92. Polley MY, Polley EC, Huang EP, **Freidlin B**, Simon R. Two-stage adaptive cutoff design for building and validating a prognostic biomarker signature. *Statistics in Medicine*, 33:5097-110, 2014
- 93. Korn EL, Dignam JJ, **Freidlin B**. Assessing treatment benefit with competing risks not affected by the randomized treatment. *Statistics in Medicine*, 34:265-80, 2015
- 94. Korn EL, **Freidlin B**. Commentary on Hey and Kimmelman. *Clinical Trials*, 12: 122-124, 2015
- 95. Korn EL. **Freidlin B**. Evaluation of chemoresponse assays as predictive marker. *British Journal of Cancer* 112:621-623, 2015
- 96. Korn EL. **Freidlin B**. Response to Comment on: Evaluation of chemoresponse assays as predictive marker. *British Journal of Cancer* 112:1978, 2015

- 97. **Freidlin B**, Little RF, Korn L. Design issues in randomized clinical trials of maintenance therapies. *Journal of the National Cancer Institute* 107(11): djv225, 2015
- 98. **Freidlin B**, Korn EL, RE: Impact of a biomarker-based strategy on oncology drug development: A meta-analysis of clinical trials leading to FDA approval. (letter) *Journal of the National Cancer Institute* 108:djv430, 2016
- 99. **Freidlin B**, Othus M, and Korn EL. Information time scales for interim analyses of randomized clinical trials. *Clinical Trials* 13:391-399, 2016
- 100. Korn EL and **Freidlin B**. Non-factorial analyses of two-by-two factorial trial designs. *Clinical Trials* 13: 651-659, 2016
- 101. Korn EL, **Freidlin B**. Reader reaction on estimation of treatment effects in all-comers randomized clinical trials with a predictive marker. *Biometrics* 73:706-708, 2017
- 102. Zhang Q, **Freidlin B**, Korn EL, Halabi S, Mandrekar S, and Dignam JJ. Comparison of futility monitoring guidelines using completed phase III oncology trials. *Clinical Trials* 14:48-58, 2017
- 103. Little RF, McShane LM, **Freidlin B**. Myeloma minimal residual disease and surrogacy (letter). *JAMA Oncology* doi: 10.1001/jamaoncol.2016.5660, 2017
- 104. **Freidlin B** and Korn EL. Sample size adjustment designs with time-to-event outcomes: a caution. *Clinical Trials* 14:597-604, 2017
- 105. **Freidlin B** and Korn EL. Rejoinder to Dr. Mehta. *Clinical Trials* 14:609-610. 2017
- 106. Korn EL, Othus M, Chen T-T and **Freidlin B**. Assessing treatment efficacy in the subset of responders in a randomized clinical trial. *Annals of Oncology* 28:1640-1647, 2017
- 107. Korn EL and **Freidlin B**. Adaptive Clinical Trials: Advantages and disadvantages of various adaptive design elements. *Journal of the National Cancer Institute* 109: dlx013, 2017
- 108. **Freidlin B** and Korn EL. Two-by-two factorial cancer treatment trials: Is sufficient attention being paid to possible interactions? *Journal of the National Cancer Institute* 109:djx146, 2017
- 109. Korn EL, **Freidlin B**. Quantitative assessment of a prognostic or predictive biomarker panel. *Journal of Biopharmaceutical Statistics* 28:264-281, 2018

- 110. Korn EL, **Freidlin B**. Interim monitoring for non-inferiority trials: minimizing patient exposure to inferior therapies. *Annals of Oncology* 29:573-577, 2018
- 111. Korn EL, **Freidlin B**. Surrogate and intermediate endpoints in randomized trials: what's the goal? *Clinical Cancer Research* 24:2239-40, 2018
- 112. **Freidlin B**, Korn EL, Abrams JS. Bias, operational bias, and generalizability in phase II/III trials. *Journal of Clinical Oncology* 36:1902-04, 2018
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- 114. Yee LM, McShane LM, **Freidlin B**, Mooney MM, Korn EL. Biostatistical and Logistical Considerations in the Development of Basket and Umbrella Clinical Trials. *Cancer Journal* 25:254-263, 2019
- 115. Korn EL, Gray RJ, **Freidlin B**. Noninferiority trials with nonadherence to the assigned randomized treatment. *Clinical Trials* 16:673-681 2019
- 116. **Freidlin B**, Korn EL. Methods for Accommodating Nonproportional Hazards in Clinical Trials: Ready for the Primary Analysis? *Journal of Clinical Oncology* 37:3455-3459, 2019
- 117. Polley M-YC, Korn EL, **Freidlin B**. Phase III precision medicine clinical trial design that integrates treatment and biomarker evaluation *JCO Precision Oncology* 3:1-9, 2019
- 118. Foster JC, **Freidlin B**, Kunos CA, Korn EL. Single-Arm Phase II Trials of Combination Therapies: A Review of the CTEP Experience 2008-2017. *Journal of the National Cancer Institute* 112:djz193, 2020
- 119. **Freidlin B**, Allegra CJ, Korn EL. Moving Molecular Profiling to Routine Clinical Practice: A Way Forward? *Journal of the National Cancer Institute* djz240, 2020

Book Chapters:

- 1. Simon R, Dixon D, Freidlin B. A Bayesian model for evaluating specificity of treatment effects in clinical trials. *Recent Advances In Clinical Trial Design*, Thall P. editor, Kluwer Academic Publishers, Boston, 1995
- 2. Simon R, Dixon D, **Freidlin B**. Bayesian subset analysis of a clinical trial for the treatment of HIV infection. *Bayesian Biostatistics*, Berry D and Stangl D. (eds.), Marcel-Dekker, New-York, 1996
- 3. **Freidlin B**, and Gastwirth JL. The application of change point tests to data occurring in fair hiring cases. *Asymptotic Methods in Probability and Statistics (ICAMPS)*, Szyszkowicz B. editor, Elsevier Science, Amsterdam, 1998
- 4. Gastwirth JL, **Freidlin B**, Miao W. The Shonubi case as an example of the legal system's failure to appreciate statistical evidence. *Statistical Science in the Courtroom*, Gastwirth JL editor, Springer, New-York, 2000
- 5. Zheng G, **Freidlin B**, and Gastwirth JL. Comparison of robust test for genetic association using case-control studies. *IMS Lecture Notes-Monograph Series*, 2006
- 6. Dancey J, **Freidlin B**, and Rubinstein L. Accelerated titration designs.

 Statistical Methods in Dose-Finding Studies, Chevret S. editor, Wiley, New-York, 2006
- 7. **Freidlin B**. Futility analysis. *Encyclopedia of Clinical Trials*, Wiley, New-York, 2007
- 8. Korn EL, **Freidlin B**. Interim analysis of phase III trials. *Oncology Clinical Trials*, Kelly and Halabi S (eds.), Demos Medical, New York, 2010
- 9. McShane LM, Korn EL, **Freidlin B**. Statistical considerations in the development and evaluation of therapeutic biomarkers in cancer. In *Handbook of Therapeutic Biomarkers in Cancer*, Yang, Dancey (eds.), Pan Stanford, Singapore, 2013.
- 10. **Freidlin B.** Futility analysis. In *Methods and Applications of Statistics in Clinical Trials: Planning, Analysis, and Inferential Methods*. Balakrishnan N editor, Wiley, New York, 2014.
- 11. Korn EL, **Freidlin B**. Outcome-adaptive randomization in early clinical trials. In *Design and Analysis of Clinical Trials for Predictive Medicine*, Matsui S, Buyse ME and Simon R (eds.), Chapter 7, CRC Press, Boca Raton, FL, 2015
- 12. **Freidlin B**. and Simon R. Adaptive clinical trial designs with biomarker development and validation In *Design and Analysis of Clinical Trials for*

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- 14. Korn EL and **Freidlin B**. Clinical Trial Designs in Oncology. In *Abeloff's Clinical Oncology*, Sixth Edition Niederhuber JE, Armitage JO, Doroshow JH, Kastan MB, and Tepper JE (eds.), New York: Elsevier. (in press)

Book reviews:

Ellenberg SS, Fleming TR, and DeMets DL. *Data Monitoring Committees in Clinical Trials*, 2002; New York: Wiley. *Biometrics*, 59:457-458, 2003